REMARKS/ARGUMENTS

Reconsideration of this Application is respectfully requested. Claims 1, 3-6, and 8-25 are pending in the present Application. In the Office Action mailed July 31, 2008, the Examiner rejected pending claims 1, 3-6, and 8-25 on various grounds. In view of the following remarks, favorable consideration and allowance of the Application is respectfully requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

A. Claims 1, 3-6, and 8-10 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,616,765 to Castro, *et al.* (the *Castro* patent).

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

> a stent delivery system including a stent having a plurality of cylindrical stent segments, the stent having a first region continuous across at least one pair of adjacent cylindrical stent segments and a second region continuous across at least one pair of adjacent cylindrical stent segments; a first coating section, the first coating section disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the first region and comprising a first polymer; and a second coating section, the second coating section disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the second region and comprising a second polymer; wherein the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 1; or

a coated stent including a stent having a plurality of cylindrical stent segments, the stent having a first region continuous across at least one pair of the adjacent cylindrical stent segments and a second region continuous across at least one pair of the adjacent cylindrical stent segments; a first coating section, the first coating section disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the first region and comprising a first polymer; and a second coating section, the second coating section disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the second region and comprising a second polymer; wherein the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 6.

At most, the *Castro* patent discloses that a composition 10 is deposited in a preselected geometrical pattern on prosthesis 12. *See* column 14, lines 65-67; Figures 13A-13H. A second composition 80 can be deposited onto prosthesis 12. *See* column 17, line 61 through column 18, line 32. The *Castro* patent fails to disclose a first and a second region each continuous across at least one pair of adjacent cylindrical stent segments, a first and a second coating section each completely covering the outer surface of adjacent cylindrical stent segments in their respective regions, where the regions and coating sections are discrete, as claimed.

In the Response to Arguments section of the present Office Action dated July 31, 2008, on page 8, the Examiner asserts "words of the claim must be given their plain meaning unless Applicant has provided a clear definition in the specification." The Applicant respectfully disagrees.

The Examiner's interpretation of "cylindrical stent segments" and "coating section" as claimed incorrectly disregards the guidance of the specification. MPEP Chapter 2111 cited by the Examiner clearly states the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). The PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account

whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. *See* MPEP 2111. No explicit definition is required. The meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in the context in the specification. *See* MPEP 2111.01. The specification cannot be disregarded.

The present Application provides additional support for the Applicant's meaning of "cylindrical stent segments" beyond that support previously presented below. "Cylindrical" is used in the present Application to describe the overall stent shape. Stents are generally cylindrical shaped devices. *See* page 1, paragraph [0002]. To prevent restenosis, short flexible cylinders, or stents, constructed of metal or various polymers are implanted within the vessel to maintain lumen size. Various configurations of stents include a cylindrical tube. *See* page 1, paragraph [0004]. "Cylindrical" is used consistently in the specification to describe the shape of the stent and the stent segments and in no other way.

The present Application also does not suggest that the wire or material making up the cylindrical stent segment has any particular cross-section, such as the cylindrical cross-section asserted by the Examiner. The stent 150 can be formed through various methods. The stent 150 can be welded, laser cut, molded, or consist of filaments or fibers which are wound or braided together in order to form a continuous structure. *See* page 6, paragraph [0027]. The wire or material making up the cylindrical stent segment can have any number of cross-sections, cylindrical just being one of many and cylindrical not being particularly suggested in the present Application.

The *Castro* patent further supports the Applicant's meaning of "cylindrical stent segments." Stents are scaffoldings, usually cylindrical or tubular in shape. *See* column 1, lines 41-42. In fact, the *Castro* patent fails to disclose a segment of the stent is cylindrical as asserted by the Examiner. The perspective views of the prostheses clearly show a rectangular cross-section. *See* Figures 14A, 14B, and 15A-15D. Figures 14A and 14B are reproduced below.

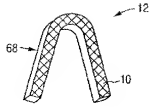


Figure 14A

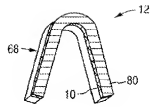


Figure 14B

This is further supported by Figures 14C-14F, which are transverse cross-sections of the strut 68. *See* Figures 14C-14F. As shown for Figures 14C and 14D reproduced below, the transverse cross-sections are generally rectangular.

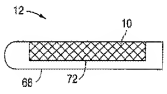


Figure 14C

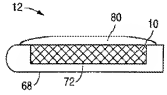
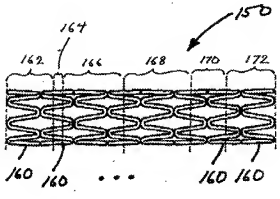


Figure 14D

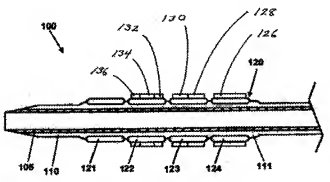
All other stent figures of the *Castro* patent show a side view, from which it is not possible to determine the cross-section. *See* Figures 7A-13H.

The Examiner's conclusion regarding the *Castro* patent fails to address the claim language of claims 1 and 6: it is the claimed stent segments which are cylindrical. The cylindrical stent segments as claimed are clearly shown in Figure 2 reproduced below.

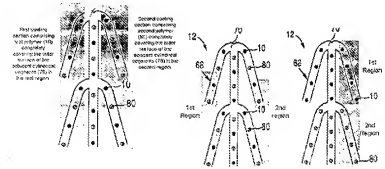


The stent 150 comprises a number of segments 160. The pattern of the stent segments 160 can be W-shaped or can be a more complex shape. *See* Figure 2; page 6, paragraph [0026]. The stent 120 may be any variety of implantable prosthetic devices capable of carrying a coating known in the art. In one embodiment, the stent 120 may have a plurality of identical cylindrical stent segments placed end to end. *See* Figure 1; page 5, paragraph [0022]. While the specification is not to be read into the claims, the verbiage of the claims must be considered to possess their ordinary usage as would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in Applicant's specification. *See* MPEP 2111.

The illustration provided by the Examiner on page 4 of the Office Action dated January 2, 2008, also ignores the claim language of claims 1 and 6, which requires that the first an second coating sections completely cover the outer surface of the adjacent cylindrical stent segments in their respective discrete regions. The stent with an intermittent coating of the present invention provides a coating having a plurality of discrete coating sections disposed on a stent, i.e., an intermittent coating. The individual coating sections can contain different drugs or therapeutic agents, can be made of different polymers, can be made with different solvents, or combinations thereof. *See* page 4, paragraph [0020]. The stent segments can be provided with one or more discrete coating sections as desired. Stent segment 121 is shown without a coating. Coating section 126 is disposed on stent segment 124, coating sections 128 and 130 are disposed on stent segment 123, and coating sections 132, 134, and 136 are disposed on stent segment 122. *See* Figure 1 (reproduced below); page 5, paragraph [0023].



As shown by the Examiner's illustration, reproduced below, the *Castro* patent at most discloses composition 10, 80 in cavities of the prosthesis 12, but fails to disclose coating sections completely covering the outer surface of the adjacent cylindrical stent segments as claimed. The coating of the *Castro* patent is made of individual dots which fail to cover the surface 70. The coating section as claimed is not an abstract area, but is the actual coating on the stent. The meaning of the term "coating section" must allow for the usage of the term in the context in the specification. *See* MPEP 2111.01.



Claims 3-5 and claims 8-10 depend directly or indirectly from independent claims 1 and 6, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their independent claims.

Regarding claims 5 and 10, the Applicant respectfully asserts that Figure 13F of the *Castro* patent fails to disclose a spotted pattern as defined by Figure 4 and paragraph [0030] of the present Application.

Withdrawal of the rejection of claims 1, 3-6, and 8-10 under 35 U.S.C. §102(e) as being anticipated by the *Castro* patent is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a

claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicants respectfully assert that the cited references fail to teach or suggest all the claim limitations.

B. Claims 11-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the C*astro* patent.

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

a method for producing a coated stent including providing a stent having a plurality of cylindrical stent segments, the stent having a first region continuous across at least one pair of adjacent cylindrical stent segments and a second region continuous across at least one pair of adjacent cylindrical stent segments; mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; applying the first polymer solution to the first region to form a first coating section completely covering the outer surface of the adjacent cylindrical stent segments in the first region; mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and applying the second polymer solution to the second region to form a second coating section completely covering the outer surface of the adjacent cylindrical stent segments in the second region, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 11;

a system for producing a coated stent from a stent having a plurality of cylindrical stent segments, the stent having a first region continuous across at least one pair of the adjacent cylindrical stent segments and a second region continuous across at least one pair of the adjacent cylindrical stent segments, including means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; means for applying the first polymer solution to the first region to form a first coating section completely covering the outer surface of the adjacent cylindrical stent segments in the first region; and means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and means for applying the second polymer solution to the second region to form a second coating section completely covering the outer surface of the adjacent cylindrical stent segments in the second region, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 18; or

a coated stent including a stent having a plurality of cylindrical stent segments, the stent having a discrete first region continuous across at least one pair of the adjacent cylindrical stent segments and a discrete second region continuous across at least one pair

of the adjacent cylindrical stent segments; a first polymer including a first therapeutic agent, the first polymer disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the discrete first region as a first coating section; and a second polymer including a second therapeutic agent, the second polymer disposed on and completely covering the outer surface of the adjacent cylindrical stent segments in the discrete second region as a second coating section, wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 22.

The *Castro* patent discloses that a composition 10 is deposited in a preselected geometrical pattern on prosthesis 12. *See* column 14, lines 65-67; Figures 13A-13H. A second composition 80 can be deposited onto prosthesis 12. *See* column 17, line 61 through column 18, line 32. As discussed in detail in Section A above, the *Castro* patent fails to disclose a first and a second region each continuous across at least one pair of adjacent cylindrical stent segments, a first and a second coating section each completely covering the outer surface of adjacent cylindrical stent segments in their respective regions, where the regions and coating sections are discrete, as claimed. In addition, the *Castro* patent fails to disclose the first region having a longitudinal length greater than the diameter of the stent in an expanded state, as correctly concluded by the Examiner on pages 3 and 5 of the Office Action dated July 16, 2007.

Claims 12-17; claims 19-21; and claims 23-25 depend directly or indirectly from independent claims 11, 18, and 22, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 11-25 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the Application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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